[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request:

National Institutes of Health Information Collection Forms to Support Genomic Data Sharing for Research Purposes

AGENCY: National Institutes of Health (NIH), PHS, DHHS.

ACTION: Request for comments

SUMMARY: Under the provisions of Section 3507(a) (1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the Federal Register on October 5, 2012 (77 FR 61008), and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. NIH may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: National Institutes of Health Information Collection Forms to Support Genomic Data Sharing for Research Purposes; *Type of Information Collection Request*: New; *Need and Use of Information Collection*: The NIH mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability. The sharing of research data supports this mission and is essential to facilitate the translation of research results into knowledge, products, practices, and procedures that improve human health.

By enabling secondary research questions to be addressed, data sharing maximizes the public benefit achieved through research investments. NIH's *Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS)* was established to enable the full value of GWAS data to be realized. GWAS data are maintained in a central data repository, the database of Genotypes and Phenotypes (dbGaP), which is administered by the National Center for Biotechnology Information (NCBI), part of the National Library of Medicine at NIH.

As stipulated in the NIH GWAS Policy, all principal investigators (PIs) who receive NIH funding to conduct genomic research are expected to register studies with genomic data in dbGaP. The nature of the genomic, phenotypic, and other associated data generated through large-scale human genomic studies requires responsible stewardship throughout research and data sharing activities. Since the data being collected and shared are from human research participants, the protection of participant interests is paramount. PIs submitting data to dbGaP must describe any limitations on sharing the data, as defined in the informed consent provided by

the participants from whom the data were originally collected. PIs must also provide basic study information such as the type of data that will be submitted to dbGaP and a description of the study.

Researchers interested in using dbGaP data for secondary research must submit a request through dbGaP and be granted permission from the relevant NIH Data Access Committees to access the data. As part of the request process, researchers must provide information such as a description of the proposed research use of the dbGaP datasets, a data security plan, and a Data Use Certification, in which the researcher agrees to the terms and conditions for use of the data. NIH has developed online forms, which will be available through dbGaP, in an effort to reduce the burden for researchers to complete the study registration, data submission, and data access processes.

Frequency of Response: As necessary.

Description of Respondents: PIs and senior officials from their institutions.

Estimate of Burden: The burden associated with this information collection is calculated in two parts: (1) the burden associated with registering genomic studies and submitting data to dbGaP and (2) the burden associated with applying for genomic data in dbGaP. The annual reporting burden for study registration and data submission is as follows: *Estimated Number of Respondents*: 100; *Estimated Number of Responses per Respondent*: 1; and *Estimated Total Annual Burden Hours Requested*: 63. The annual cost to respondents is estimated at $2,506. The annual reporting burden for applying for genomic data in dbGaP is as follows: *Estimated Number of Respondents*: 1, 266; *Estimated Number of Responses per Respondent*: 2; and *Estimated Total Annual Burden Hours Requested*: 1,583. The annual cost to respondents is estimated at $63,452. There are no capital, operating, or maintenance costs to the respondents.

Type of Respondent	Estimated Number of Respondents	Estimated Number of Responses Per Respondent	Average Burden Per Response (in Hours)	Estimated Total Annual Burden Hours
Study Registration and Data Submission				
PI	50	1	45/60	38
Senior Official	50	1	30/60	25
Total	100			63
Data Access Request				
PI	633	2	45/60	950
Senior Official	633	2	30/60	633
Total	1,266			1,583

Request For Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instrument, contact: Sarah Carr, Acting Director, Office of Clinical Research and

Bioethics Policy, Office of Science Policy, NIH, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892; telephone 301-496-9838; fax 301-496-9839; or email GWAS@od.nih.gov, Attention: Ms. Carr.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: January 18, 2013

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Sarah Carr
Acting Director, Office of Clinical Research and Bioethics Policy, Office of Science Policy
National Institutes of Health

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